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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,165	01/28/2004	James Matthew Stephens	25692-00003	3396

33772 7590 12/20/2005
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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,165

Applicant(s)

STEPHENS, JAMES MATTHEW

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Claims 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite since it uses the open language of “also including”. However, claim 1, from which claim 2 depends, uses the partially closed language of “consisting essentially of”. It is not clear what components the composition of claim 1 excludes and what components it can include as “nonessential” components. It is not clear how “consisting essentially of” in claim 1 is being interpreted since claim 2 uses open language. See this same problem in claim 6. For the purposes of examining claims 1 and 2, “consisting essentially of” will be considered open to the inclusion of other components.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haddad (US 2004/0077106) in view of any one of Adamczyk et al, Bernardin or Melius et al.

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Haddad teaches of a synthetic urine and a method for making it. The synthetic urine comprises appropriate amounts of individual components of human urine such that the sample appears to be a genuine human urine. The synthetic urine comprises creatinine in normal levels, salts such as chlorides, phosphates and sulfates, and water to dilute the formulation. The synthetic urine has a specific gravity between about 1.00 and 1.035 g/cm³, and a pH between about 4 and 9. The urine can also include urea therein, and optionally a buffer to establish or maintain a pH of 4 to 9. Haddad teaches that a preservative can also be included in the artificial urine composition. The urine composition is preferably packaged in a sealed container such as a sealed pouch or airtight container. To form the urine composition, creatinine and salts are dissolved in water, and the resulting solution is stirred, shaken or mixed. Optional components of urea, a buffer and a preservative are also dissolved in the water. See paragraphs nos. 0012-0020 and 0024-0031 in Haddad. Haddad fails to teach that the water used to make the synthetic urine has a pH between 3 and 10, and fails to teach that the preservative serves to minimize sepsis or bacterial growth in the synthetic urine.

Adamczyk et al teach of an artificial urine composition that contains therein urea, creatinine, water and the preservative sodium azide at a pH of 7.3-7.5. See lines 13-21 in column 6 of Adamczyk et al. Sodium azide is a known bacterial inhibitor.

Bernardin teaches of a synthetic urine that comprises urea and a sodium azide preservative. See lines 1-4 in column 8 of Bernardin.

Melius et al teach of a synthetic urine composition that comprises various different salts, urea, water and Germall 115 preservative. See lines 12-28 in column 6 of Melius et al. Germall

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preservatives are known anti-bacterial compounds that serve to kill bacteria and minimize sepsis in a solution.

Based upon the combination of Haddad with any one of Adamczyk et al, Bernardin or Melius et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use any one of the anti-bacterial preservatives taught by Adamczyk et al, Bernardin or Melius et al as the preservative in the synthetic urine composition taught by Haddad since each of Adamczyk et al, Bernardin or Melius et al teach that it is known in the art to include in synthetic urine compositions antibacterial preservatives or biocides that preserve the urine by killing bacteria therein and preventing sepsis or bacterial growth. It also would have been obvious to one of ordinary skill in the art to use water having a pH between 3-10 to make the synthetic urine taught by Haddad since Haddad teaches that the synthetic urine should have a pH between these values, and the use of water already having a pH in this range avoids the use of a buffer to establish the required pH level.

5. Applicant's arguments filed October 6, 2005 have been fully considered but they are not persuasive.

Applicant argues the rejection of the claims made under 35 USC 112, second paragraph in the previous Office action mailed on January 24, 2005 by stating that the closed language of claim 1 already limits the depending claims, and the term "including" in claims 2 and 6 only serves to indicate a single additional element. This argument is not found persuasive since if claim 1 uses the closed language of "consisting essentially of", then the claim is not open to the addition of any more essential components to the composition such as urea recited in claims 2 and 6. If urea is an essential component of the synthetic urine composition, then it should be

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recited in independent claim 1 using the closed language along with the other essential components of the composition.

Applicant argues the rejection of the claims under 35 USC 103 as being obvious over Haddad in view of any one of Adamczyk et al, Bernardin, Melius et al or Watanabe et al by stating that Haddad fails to teach that the preservative in the synthetic urine composition is a biocide that kills microorganisms. In response to this argument, it is noted that the primary reference to Haddad does not teach that the preservative is a "biocide" as defined by Applicant. However, when Haddad is taken in combination with any one of the secondary references that teach of the inclusion of a known biocide into a synthetic urine composition, it would have been obvious to one of ordinary skill in the art to use as the preservative in the composition taught by Haddad any one of the known biocides taught by the secondary references since these secondary references disclose that it is advantageous to include biocides in synthetic urine compositions in order to kill any microorganisms therein and prevent the growth of microorganisms so that the urine may remain stable for a long period of time.

Applicant argues that neither reference to Adamczyk et al or Bernardin teaches that sodium azide is a biocide or a bacterial inhibitor. In addition, Applicant argues that it would not have been obvious to add the sodium azide taught by Adamczyk et al or Bernardin to the synthetic urine composition taught by Haddad since sodium azide is explosive when exposed to heat, and the synthetic urine composition of Haddad includes a heat activator in order to warm the sample. In response to these arguments, it is noted that sodium azide is a well-known biocidal material that serves to kill various microorganisms such as bacteria in samples. As evidence of this, please see the patent to McConnell et al (US Patent no. 3,880,646), which

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teaches that sodium azide kills, deactivates and regulates the growth of organisms. See the abstract and lines 18-21 in column 1 of McConnell et al. Therefore, contrary to Applicant's argument, the sodium azide taught by both Adamczyk et al and Bernardin is an inherent and well-known biocide. With regards to Applicant's argument concerning the heat instability of sodium azide, it is noted that the heat activator in the synthetic urine composition taught by Haddad only serves to heat the sample up to a temperature that is equivalent to human body temperature, i.e. about 37°C. The patent to McConnell et al teaches that sodium azide is stable at all temperatures up to 300 °C. See lines 27-29 in column 1 of McConnell et al. Therefore, it would not be expected that sodium azide at a temperature of 37°C, as used in the composition taught by Haddad, would be explosive.

Applicant argues that the reference to Melius et al is nonanalogous art since Melius et al teach of an adult incontinence device. In response to this argument, it is noted that the portion of Melius et al relied upon in the rejection teaches of a synthetic urine composition, which is what the claims as currently written recite. See lines 12-28 in column 6 of Melius et al. Therefore, this portion of Melius et al is analogous art to the instant claims. Applicant also argues that Melius et al fail to teach that the Germall preservative in the synthetic urine is a biocide. In response to this argument, it is noted that Germall is a well-known and inherent biocide that serves to kill organisms in samples, as evidenced by the patent to Keusch et al (US Patent no. 4,989,607). See lines 21-25 in column 11 of Keusch et al that teaches of common biocide materials including Germall. Therefore, it would have been obvious to one of ordinary skill in the art to use as the preservative in the composition taught by Haddad the Germall biocide taught by Melius et al since Melius et al disclose that it is advantageous to include a known biocide in a

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synthetic urine composition in order to kill any microorganisms therein and prevent the growth of microorganisms so that the urine may remain stable for a long period of time.

Applicant's arguments concerning the reference to Watanabe are persuasive, and therefore, this reference is no longer relied upon in the 35 USC 103 rejections of the claims.

For all of the above reasons, Applicant's arguments are not found persuasive.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

December 13, 2005

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1700